

**GOVERNMENT OF INDIA  
HEALTH AND FAMILY WELFARE  
LOK SABHA**

STARRED QUESTION NO:124  
ANSWERED ON:27.11.2002  
HUMAN CLINICAL TRIALS  
MANEKA SANJAY GANDHI

**Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:**

- (a) whether the Government are aware of the practice of private pharmaceutical companies conducting human clinical trials in Government hospitals in the country;
- (b) if so, the details thereof;
- (c) whether such research has been projected as a cheap option for the drugs developed abroad;
- (d) if so, the details thereof;
- (e) the details of the remuneration paid to people undergoing human clinical trials;
- (f) whether there has been any evaluation of the social benefits, if any, from such clinical trials; and
- (g) if so, the legislations under which such trials are being regulated?

**Answer**

MINISTER OF HEALTH AND FAMILY WELFARE (SHRI SHATRUGHAN SINHA)

(a)to(g): A statement is laid on the table of the Lok Sabha.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 124 FOR 27.11.2002

(a) & (b) : Yes, Sir. The clinical trials are conducted in Government as well as private Hospitals by Pharmaceutical and Research institutions. Under the provision of Drugs and Cosmetics Rules, (Schedule Y), the Human clinical trials are required to be carried out in the country before a new drug is approved for marketing for the first time and depends upon the status of the drug in other countries. Usually, limited phase-III clinical trials are required to be conducted in the country for those drugs which are already approved or marketed internationally and for which applications for market authorization in the country are submitted. These trials are usually conducted in Hospitals, (both public and private sectors) where adequate facilities, availability of patients and infrastructure are available. For indigenously developed new molecules phase-I, II and III, clinical trials are required to be conducted.

(c)&(d) : No, Sir. For the drugs developed abroad, clinical studies are conducted in respective countries. However, it has been recognised that India has the necessary potential to undertake cost effective clinical research conforming to global standards.

(e) As per Ethical Guidelines for Biomedical Research on Human Subject published by Indian Council of Medical Research (ICMR) in 2000, research subjects may be paid for inconvenience, time spent and expenses incurred in connection with their participation in the research study. Research subjects are entitled to financial or other assistance to compensate them for temporary or permanent impairment or disability.

(f) Clinical research is imperative for discovery of safe and effective drug. Introduction of new drugs over the years has helped the society to address its health care needs by providing better treatment for many diseases and disorders.

(g) Human clinical trials are covered under World Medical Association declaration of Helsinki of 1964 which has been revised from time to time. Apart from this, each country has its own regulatory requirements for conducting human clinical trials. In India clinical trials are regulated under Rule 122 DA and Sch. Y of the Drugs and Cosmetic Rules. Ethical guidelines for biomedical research on human subject have been published by ICMR in year 2000 and the guidelines for Good Clinical Practices (GCPs) have been recommended by the Ministry in December 2001. The Ethical norms to be followed in human trials include requirement of an Institutional Ethics Committee (IEC) and obtaining consent from research subjects.